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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,470

02/14/2006

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21494YP

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210 7590 12/11/2007  
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EXAMINER

KIFLE, BRUCK

ART UNIT

PAPER NUMBER

1624

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12/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,470	<b>Applicant(s)</b> THOMPSON ET AL.	
	<b>Examiner</b> Bruck Kifle	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/06 &amp; 03/07</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, 9 and 10 drawn to a compound of formula (I), (Ia), (Ib), (Ic) and a compound of claim 6 along with the corresponding pharmaceutical composition of claims 7, 9 and 10.

Group II, claim 8, drawn to a pharmaceutical composition comprising additional therapeutic agents.

Group III, claim 11, drawn to a method for treating or preventing pain, Parkinson's disease Alzheimer's disease, epilepsy, depression, anxiety, ischemic brain injury including stroke.

Group IV, claim 12, drawn to a method for treating or preventing chronic, visceral, inflammatory and neuropathic pain syndromes.

Group V, claim 13, drawn to a method for treating or preventing pain resulting from, or associated with, traumatic nerve injury, nerve compression or entrapment, postherpetic neuralgia, trigeminal neuralgia, diabetic neuropathy, cancer and chemotherapy.

Group VI, claim 14, drawn to a method for treating or preventing chronic lower back pain.

Group VII, claim 15, drawn to a method for treating or preventing phantom limb pain.

Group VIII, claim 16, drawn to a method for treating or preventing HIV- and HIV treatment-induced neuropathy, chronic pelvic pain, neuroma pain, complex regional pain syndrome, chronic arthritic pain and related neuralgias.

Group IX, claim 17, drawn to a method for treating and preventing epilepsy and partial and generalized tonic seizures.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: Groups I and II are different in scope. Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d).

Groups I and III-IX are related as product and process of using. The uses raise different issues of patentability and require separate searches in the literature. Each use has to be searched and analyzed separately to determine patentability.

During a telephone conversation with Mr. John Todaro on December 6, 2007 a provisional election was made with traverse to prosecute the invention of group I, claims 1-7, 9 and 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8 and 11-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

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process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Duplicate Claims***

Applicant is advised that should claim 7 be found allowable, claims 9 and 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Intended uses do not have patentability weight.

***Claim Rejections - 35 USC § 112***

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) The independent claims end with the phrase “and pharmaceutically acceptable salts thereof, and individual and diastereomers thereof.” This is improper Markush language. The phrase “or a pharmaceutically acceptable salt thereof, or diastereomer thereof.” The phrase “and individual and diastereomers thereof” is unclear. What is Applicants intention?
- ii) The definition of “Y” in claim 1 is unclear. The orientation of the second and third fragments is unclear. Is the cyclopropyl attached to Z or to R<sup>1</sup>? In the third fragment, it appears that C’ and C” are attached to the phenyl ring to form a bicyclic ring system. It is unclear what is meant by “directly or indirectly bound to R<sup>1</sup>” really means. A clarification is required.
- iii) The variables “Z” and “W” are divalent. The groups embraced, therefore, also need to be named as divalent groups. Thus, alkylene, instead of alkyl and alkenylene in place of alkenyl should be the groups.
- iv) When “an individual carbon atom in A and an individual carbon atom in B optionally bridge said ring” it is unclear what atoms are present to form such bridge. Is only a bond linking such two atoms or are any linking atoms present. If so, which atoms are intended?

Claim 6 has approximately 140. This number of compounds cannot be considered a reasonable number according to rule 1.140(a). In re Fressola, 22 USPQ 2nd 1828, indicates that the Examiner may reject for Applicants failure to follow a Rule.

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See also MPEP rule 1.141(a) reproduced below.

1.141 Different inventions in one national application.

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form ( 1.75) or otherwise include all the limitations of the generic claim.

Some of the compounds may not be compounds of claims 1-5 (see, for example, page 145, second row, first compound).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruck Kifle/  
Primary Examiner  
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December 7, 2007